

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-903-200-2103

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
certifies that the manufacturer:

Biotech GmbH
Hagenauer Str. 17-19
65203 Wiesbaden
Germany

for the products / product category:

Sterile and non-sterile orthopaedic implant systems

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **NE/1010/2021**

For placing on the market of class III products covered by this certificate, EC Design-Examination Certificates according to Directive 93/42/EEC on Medical Devices, Annex II (4) are required.

This certificate is valid until **2024-05-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 2

First issued: 2021-03-09

Budapest, 2021-05-25


László Imre
Managing Director



EMKI 2758

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu



ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate No. 5-903-200-2103

The certificate is valid for the following manufacturing sites / facilities:

Biotech GmbH

Hagenauer Str. 17-19
65203 Wiesbaden, Germany

Biotech GmbH Magyarországi Fióktelepe

Petőfi Sándor utca 43-47
2049 Diósd, Hungary

The certificate is valid for the following products:

<i>Sterile and non-sterile orthopaedic implant systems</i>	<i>Class</i>
Biotech Sterile Knee Endoprosthesis Systems	III
Instruments and Trial Tray for Biotech Sterile Knee Endoprosthesis Systems	IIa
Biotech Sterile Hip Endoprosthesis Systems	III
Instruments and Trial Tray for Biotech Sterile Hip Endoprosthesis Systems	IIa
Biotech Modular Shoulder System (BMS)	III
Instruments and Trial Tray for Biotech Modular Shoulder System (BMS)	IIa
Biotech Traumatological Implant Systems for Osteosynthesis	IIb
Biotech Pectus Bar Correct System	IIb
Biotech Spinal Implant System	IIb

The detailed product list is kept by NEOEMKI LLC. under No. 1010/2020.

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